UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS

PRELIMINARY STATEMENT

On the eve of the close of discovery, Plaintiffs Janine Ali and Gilda Hagan-Brown -- who each allegedly used Cymbalta for approximately six months in 2012 or 2013 -- seek extensive documents dating back twenty to thirty years regarding a separate Eli Lilly and Company ("Lilly") product, Prozac, that neither Plaintiff ever used. Plaintiffs incorrectly claim that Prozac marketing documents will establish that Lilly was not "upfront and forthright" about the risk of symptoms upon abrupt discontinuation of Cymbalta. Pls. Mem. at 1. This premise of Plaintiffs' motion is fundamentally flawed and simply false. Since Cymbalta was first approved by the U.S. Food and Drug Administration ("FDA") in 2004, its label has included a detailed, three-paragraph warning about precisely the risks that Plaintiffs have alleged in their complaint. The label in place at the time of Plaintiffs' prescriptions was approved by the FDA in 2011 and stated as follows:

> **5.7 Discontinuation of Treatment with Cymbalta**
>
> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the

> dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Cymbalta Package Insert at 7 (Sep. 2011), Declaration of Brett C. Reynolds ("Reynolds Decl.") (May 27, 2015), Ex. 1.

Moreover, Lilly scientists published a peer-reviewed article in the Journal of Affective Disorders in 2005, seven years before either Plaintiff took Cymbalta, which detailed the discontinuation-emergent adverse events studied in Lilly's clinical trials of Cymbalta. *See* Pls. Ex. 9. That article noted that discontinuation symptoms are "common following antidepressant treatment,"[1] and that "[s]ignificantly more duloxetine-treated patients (44.3%) reported at least 1 DEAE [discontinuation-emergent adverse event] than placebo-treated patients (22.9%), with dizziness being the most common symptom." *Id.* at 1, 5. Far from hiding relevant information, therefore, Lilly not only provided a detailed warning about discontinuation symptoms in Cymbalta's FDA-approved label, but made publicly available, in a peer-reviewed journal article, the precise data that Plaintiffs contend Lilly was hiding.

Because Plaintiffs' claims that Lilly hid clinical trial data and failed to warn about discontinuation symptoms in its label are demonstrably false, the Court should reject Plaintiffs' proffered inferential leap -- that additional discovery about the marketing and sales of Prozac, a different drug manufactured by Lilly, somehow bears on Lilly's conduct with respect to the Cymbalta warning.

[1] Indeed, the risk of discontinuation symptoms following the use of antidepressants has long been known in the medical community. *See* American Psychiatric Association, Practice Guideline for the Treatment of Patients With Major Depressive Disorder at 40 (2010), available at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

Even if Plaintiffs' claims of the purported inadequacy of Lilly's Cymbalta warning *were* true,[2] the discovery that Plaintiffs seek would have no relevance. All of Plaintiffs' claims hinge on the allegation that Lilly's detailed, three-paragraph warning of discontinuation symptoms is inadequate. But where, as here, there is no suggestion that Plaintiffs or their physicians read, relied upon, or even considered Prozac and its labeling, only the *Cymbalta* labeling is relevant to this Court's and a jury's determination as to the adequacy of Lilly's warning concerning Cymbalta discontinuation symptoms. Cymbalta's label either stands or falls on its own: it is either adequate and accurate or not, by its own terms.

Finally, the discovery that Plaintiffs request is unduly burdensome to Lilly. It requires searching and producing documents from up to thirty years ago that are not kept in a centralized fashion, many of which may be in hard copy archives. Given Plaintiffs' delay in serving these requests and contesting Lilly's responses, moreover, any further productions would need to be conducted on an expedited schedule outside the close of discovery, which has already been extended once.

The Court should therefore reject Plaintiffs' attempts to leverage this case into a discovery vehicle for irrelevant documents related to an entirely different drug.

BACKGROUND

Since the beginning of this litigation, Plaintiffs have made vague, unsupported inferences about the alleged relationship between Lilly's research and marketing of Prozac and its research and marketing of Cymbalta. Indeed, Plaintiffs referenced Prozac briefly in their complaints.

[2] Lilly vigorously maintains that its FDA-approved label, including the discontinuation warning, is and always has been adequate. Indeed, the only court to rule on the issue has held that Cymbalta's discontinuation warning is adequate as a matter of law. *See McDowell v. Eli Lilly and Co.*, No. 13-cv-03786, -- F. Supp. 3d ---, 2014 WL 5801604 (S.D.N.Y. Nov. 7, 2014).

(Compl. ¶ 17.) Moreover, by the time that the complaints in these matters were filed, Plaintiffs' counsel, acting in related litigation, had already requested and received discovery on particular types of Prozac market research, *see* Order, *Saavedra v. Eli Lilly and Co.*, No. 2:12-cv-9366-SVW-MAN, dkt. 120 (C.D. Cal. Jan. 22, 2014), Reynolds Decl., Ex. 2, as well as Prozac post-marketing safety data and medical education materials relating to discontinuation symptoms, *see* Reynolds Decl., Ex. 3. By stipulation, all of that discovery may be used by Plaintiffs here.[3]

In a related, earlier-filed Cymbalta discontinuation case, counsel also received a declaration from Lilly's Senior Director of Market Research explaining the parameters of Lilly's market research database (called "Singlepoint"), which contains "completed market research studies" "from 2002 to the present." Declaration of Kathleen Pearson, *Saavedra*, dkt. 118-1, at 3 (C.D. Cal. Jan. 10, 2014), Reynolds Decl., Ex. 4. The declaration further noted that "[b]ecause of limited systematic data capture prior to January 2002, Lilly may not have access to market research studies completed prior to 2002." *Id.* Lilly has produced to Plaintiffs the available Singlepoint data; thus, Plaintiffs have in their possession market research studies related to Prozac dating back to 2002, a decade before either Plaintiff first took Cymbalta.

Shortly after filing the *Ali* and *Hagan-Brown* complaints, Plaintiffs' counsel deposed in related litigation Dr. Sharon Hoog, a medical advisor on Cymbalta who had previously worked on Prozac. Plaintiffs' counsel spent a significant portion of Dr. Hoog's deposition asking her

[3] Prozac-related discovery is but a small portion of the discovery that Plaintiffs have already taken. In response to requests for production of documents served on Lilly in this and related cases, Lilly has produced to Plaintiffs over 3 million pages of documents. Plaintiffs in this and related actions -- represented by the same counsel -- have also taken eleven depositions of Lilly employees, including four 30(b)(6) depositions covering 46 discrete topics and sub-topics. Plaintiffs have therefore had ample opportunity to pursue discovery, and because of the stipulated use here of discovery taken in other cases with far lengthier discovery periods, Plaintiffs have been able to take far more discovery over a much longer period of time than otherwise might have been available in this district.

about her Prozac research. *See* Deposition of Sharon L. Hoog, M.D. ("Hoog Depo.") at 16:5-17:6, 69:12-74:10, 85:18-99:10 (Dec. 10, 2014) [Pls.' Ex. 19]. Like the document discovery to which Plaintiffs have access, that deposition testimony is also part of the record in these two cases.

Despite being long aware of the alleged importance of Prozac to their theory of the case, having had Prozac-related documents in their possession since November 7, 2014, and having served 105 Requests for Production on Lilly on February 4, 2015, Plaintiffs did not seek Prozac-related discovery in this matter until April 15, 2015, 30 days before discovery was originally scheduled to close. At that time, Plaintiffs requested that Lilly produce:

> **2ND SET, RFP NO. 1**: Please produce the results, summaries, and/or presentations concerning market surveys and/or focus groups for PROZAC that mention, measure, or refer to WITHDRAWAL or discontinuation symptoms.
>
> **2ND SET, RFP NO. 2**: Please produce all marketing plans, market analyses, pricing studies, patient segmentation studies, conjoint studies / discrete choice studies, and/or any form of marketing evaluation of PROZAC that mention or discuss the issue of WITHDRAWAL or discontinuation symptoms.
>
> **2ND SET, RFP NO. 3**: Please produce all marketing and/or sales documents that discuss, mention, or compare the WITHDRAWAL profile of Prozac to other antidepressants, including but not limited to CYMBALTA, Zoloft, Effexor, Paxil, Celexa, and Lexapro.

Pls.' Second Set of Requests for Production at 8, [Pls.' Ex. 13].

At Plaintiffs' request, and mindful of this Court's emphasis on timely completion of discovery, Lilly served detailed Objections to Plaintiffs' Prozac-related requests for production on April 30, 2015, not merely objecting to Plaintiffs' requests where appropriate but explaining precisely what Lilly intended to produce: "Subject to the foregoing objections, Lilly will produce results, summaries, or presentations of market surveys and/or focus groups for Prozac that mention, measure, or refer to discontinuation-emergent adverse events and that can be

located through a reasonably diligent search of Lilly's Singlepoint market research database." Def.'s Objections to Pl.'s Second Set of Requests for Production of Documents at 3-5 (Apr. 30, 2015), [Pl.'s Ex. 15]. Thus, Plaintiffs have known since April 30, three weeks prior to filing the instant motion, precisely what Lilly intended to produce, and that the productions from Lilly's Singlepoint database would include only documents after 2002. Lilly reiterated its intent to produce these materials in its Responses of May 15. *See* Def.'s Responses to Pl.'s Second Set of Requests for Production of Documents at 2-3 (May 15, 2015), [Pl.'s Ex. 16]. Accordingly, and having heard no response or objections from Plaintiffs about its planned production, Lilly produced the documents responsive to these requests on May 18 and 19.

On Friday, May 15, 2015 at 9:12 p.m., without any prior discussion with Lilly, Plaintiffs also served by email a notice of a second Rule 30(b)(6) deposition. Pl.'s Notice to Take Videotaped Oral Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) (May 15, 2015), Reynolds Decl., Ex 5. The third and fourth noticed 30(b)(6) deposition topics were, respectively, "Lilly's marketing efforts to promote Prozac because of its relatively lower risk of causing discontinuation-emergent adverse events" and "[m]arketing documents produced in response to Plaintiff's Second Set of Requests for Production, Nos. 1-3." *Id.* Ex. A at 3-4. The third topic had seven subparts, including questions about sales representative materials, training, market research, continuing medical education for physicians, patient education, and comparisons to any other antidepressant. *See id.* The deposition was noticed for May 28. *Id.* Lilly informed Plaintiff on May 18 that it believed the notice was impermissible under the Federal Rules, untimely, and that the Prozac marketing-related topics were irrelevant and unduly burdensome,

and that it intended to move to quash the notice.[4] Email from Brian Stekloff to R. Brent Wisner (May 18, 2015), Reynolds Decl., Ex. 6.

Plaintiffs requested a meet-and-confer on both the document production and their 30(b)(6) notice on May 19, 2015. Following that meet-and-confer, Lilly informed Plaintiffs that it would be moving forward with its motion to quash the notice. *See* Email from Brian Stekloff to R. Brent Wisner (May 20, 2015), [Pl.'s Ex. 18]. Plaintiffs subsequently withdrew the deposition notice but stated that in its stead they would file a motion to compel production of documents. *See* Email from R. Brent Wisner to Brian Stekloff (May 21, 2015), [Pl.'s Ex. 18]. The instant motion was filed on May 22, 2015, one week before discovery is scheduled to close in these matters.

LEGAL STANDARD

Discovery, including that sought in requests for production, is limited in scope by Federal Rule of Civil Procedure 26(b). Discovery is permitted if it is "relevant to any party's claim or defense" or if the party seeking the discovery can show both good cause and its "relevan[ce] to the subject matter involved in the action." Fed. R. Civ. P. 26(b)(1). Moreover, if "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues," the court must limit the extent of that discovery. Fed. R. Civ. P. 26(b)(2)(C)(iii). Finally, "upon motion of a party and 'for good cause shown,' the court in the district in which a deposition is to be taken may 'make

[4] Indeed, various federal courts have made clear that a party may not serve a second Rule 30(b)(6) deposition notice without leave of court. *See, e.g., Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 192 (1st Cir. 2001); *State Farm Mut. Auto. Ins. Co. v. New Horizon, Inc.*, 254 F.R.D. 227 (E.D. Pa. 2008).

any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense,' including an order that the discovery not be had." *Nicholas v. Wyndham Int'l*, 373 F.3d 537, 543 (4th Cir. 2004) (quoting Fed. R. Civ. P. 26(c)).

LEGAL ARGUMENT

I. Plaintiffs' Proposed Discovery Has No Relevance to Plaintiffs' Claims

The Prozac-related discovery that Plaintiffs seek here is not relevant. First, Prozac discovery has no relevance to these particular Plaintiffs' injuries, because it is undisputed that neither Plaintiff ever took Prozac or ever considered taking Prozac as an alternative to Cymbalta. Second, and more broadly, discovery about Prozac marketing and sales in no way supports or relates to Plaintiffs' claims that Lilly had notice of the risk of discontinuation events from clinical trials, or that differences between Cymbalta and Prozac clinical trials establish Lilly's alleged misbehavior.

A. Prozac Discovery Is Irrelevant to the Injuries Alleged by Ali and Hagan-Brown

As an initial matter, there is no dispute that Plaintiffs never took or were prescribed Prozac. Nor is there any record evidence that Plaintiffs or their physicians considered Prozac as a possible treatment for Plaintiffs, that Plaintiffs or their physicians relied in any way on Prozac marketing (or even Cymbalta marketing), or that Plaintiffs would have taken Prozac but for some alleged deficiency in Cymbalta's marketing. This is true not only as a matter of the factual record related to Plaintiffs' injuries, but also in the context of the differing indications which Prozac and Cymbalta are approved to treat. Both Plaintiffs were prescribed Cymbalta to treat fibromyalgia. *See* Ali Compl. ¶ 31, Hagan-Brown Compl. ¶ 31. Cymbalta is approved by FDA for the treatment of fibromyalgia, but Prozac is not. Prozac is approved only for the treatment of Major Depressive Disorder, Obsessive Compulsive Disorder, Bulimia Nervosa, Panic Disorder,

and other forms of depression. *See* Prozac Package Insert at 1 (Oct. 2014), Reynolds Decl., Ex. 7. Thus, Prozac was unlikely ever to be an alternative choice for Plaintiffs and their physicians, and as such discovery related to Prozac cannot bear on Plaintiffs' claims.

Moreover, Cymbalta was approved by the FDA in 2004 and taken by Plaintiffs beginning only in 2012. As explained above, Lilly's Singlepoint market research database, from which it has produced documents responsive to Plaintiffs' Prozac requests, contains market research documents from 2002 to the present. Thus, Plaintiffs already have documents responsive to their requests covering the period during which Cymbalta was marketed and sold, and for the period during which they themselves took Cymbalta. Plaintiffs' motion makes no showing as to how discovery of earlier marketing materials -- including documents nearly 30 years old, following Prozac's first approval in 1987 -- could have any additional relevance to their claims that the *Cymbalta* label inadequately warned of the risk of discontinuation symptoms in 2012. *See, e.g.*, *Hajek v. Kumho Tire Co.*, No. 08-CV-3156, 2010 WL 503044, at *8 (D. Neb. Feb. 8, 2010) (sustaining defendant's objection to overbroad and burdensome discovery requests where defendant limited document production to the type of tire in the subject accident); *Diaz v. Goodyear Tire & Rubber Co.*, No. 07-353-B-M2, 2009 WL 1298219, at *3 (M.D. La. May 8, 2009) (denying motion to compel to the extent it sought documents and information about types of tires other than that used in the subject accident).

Although Plaintiffs anticipated this response to their motion, *see* Pls. Mem. at 14-16, they do not and cannot seriously counter it. Instead, Plaintiffs offer only vague suggestions that discovery into Prozac should be allowed because there was no "Chinese Wall" within Lilly separating Prozac and Cymbalta, and that some researchers who worked on Cymbalta also worked on Prozac. There is no support, however, and Plaintiffs have provided none, for the

contention that discovery is permissible merely where employees who have worked on the product at issue in a products liability case have also worked on other products about which a plaintiff seeks information. The fact that some scientists and medical employees worked on both products, and even the fact that Lilly manufactured two products in the same broad class of antidepressants, does not justify throwing open discovery to include both Cymbalta and Prozac. Taking Plaintiffs' arguments at face value, though, would lead to just such a result, effectively allowing discovery of *any* medication manufactured by a pharmaceutical company so long as a plaintiff can articulate *some* possible connection within the company between it and the medication that is the subject of the lawsuit, such as an argument that the company's marketing of the earlier product caused it to learn that some particular feature was of interest to consumers. The federal discovery rules are not so broad. *See, e.g., English v. Gen. Elec. Co.*, 977 F.2d 572, at *3 (4th Cir. 1992) (affirming the denial of a motion to compel where a would-be whistleblower of safety violations sought discovery concerning *prior* safety violations and disciplinary actions the defendant had taken against *other* employees).

B. Prozac Discovery Is Irrelevant to Lilly's Notice of Discontinuation Events or to Lilly's Design of Clinical Trials

Setting aside Prozac's irrelevance to these particular Plaintiffs' claims, Plaintiffs allege that their proposed Prozac discovery indicates Lilly's awareness of the risk of discontinuation events and that it demonstrates that Lilly did not adequately research discontinuation events. But this is sleight-of-hand. Plaintiffs' motion seeks information about Prozac *marketing*. Lilly's knowledge of and research into discontinuation events are the subject of *clinical trials*, about which Plaintiffs already have extensive discovery. Plaintiffs should not be permitted to shoehorn the arguable relevance of clinical trials to obtain discovery about Prozac marketing -- marketing which, as noted above, cannot possibly bear on Plaintiffs' prescription and use of Cymbalta.

Moreover, Lilly's marketing of Cymbalta (which itself had no effect on Plaintiffs' use) has already been the subject of extensive discovery.

First, Prozac's marketing plans are irrelevant to establishing Lilly's notice of the risk of discontinuation events. There is no dispute in this case that Lilly had studied, warned of, and published articles about the risk of discontinuation events related to Cymbalta.[5] The entire Cymbalta clinical trial program was constructed to carefully capture and evaluate the occurrence of these discontinuation-emergent adverse events, and the Cymbalta Physician Package Insert has included a detailed, three-paragraph warning of the possibility of discontinuation symptoms since the product's launch. Cymbalta Package Insert at 6-7 (Sep. 2011), Reynolds Decl., Ex. 1. Indeed, the article on which Plaintiffs' claims are premised reflects Lilly's close attentiveness to the occurrence of discontinuation-emergent adverse events in patients ceasing Cymbalta therapy. David G. Perahia et al., *Symptoms following abrupt discontinuation of duloxetine treatment in patients with major depressive disorder*, 89 J. of Affective Disorders 207 (2005), Pls. Ex. 9; Compl. ¶¶ 19-20.

Second, Plaintiffs' allegation that Lilly manipulated its Cymbalta clinical trials by using different methodologies than those used for Prozac actually underscores rather than refutes the utter irrelevance of the requests at issue here. Plaintiffs are seeking discovery on Prozac *marketing*, not on Prozac *clinical trials*. And although Plaintiffs cite commonalities between Lilly's Cymbalta and Prozac teams, they are all medical personnel and scientific researchers, not marketers. *See* Pls. Mem. at 13. Similarly, Judge Mumm's decision to grant Plaintiffs some discovery on Prozac in the California cases rested on his opinion that "Lilly's knowledge of

[5] As noted above at note 1, it is well known in the medical community that Cymbalta, like the other medications in its class, has a risk of discontinuation symptoms.

withdrawal risks as demonstrated *by the earlier studies*" might potentially have affected Lilly's clinical trials. *See* Hr'g Tr., *Carter v. Eli Lilly & Co.*, at 7:18-22 [Pl.s' Ex. 20]. Prozac's 1980s and 1990s marketing plans and materials cannot shed any light on Cymbalta's clinical trials, which were designed and run by scientists and medical personnel, and about which Plaintiffs have already received extensive discovery.[6]

Third, Plaintiffs' theory that Lilly improperly minimized the risk of discontinuation-emergent adverse events in its Cymbalta marketing materials as compared to Prozac marketing materials would, if true, be supported by *Cymbalta* marketing materials, not Prozac marketing.[7] And even though Lilly does not believe that even Cymbalta marketing materials are relevant to Plaintiffs' claims, Lilly has already produced to Plaintiffs a wide variety of Cymbalta marketing-related materials, including over 18,400 documents that reflect submissions to the FDA of all advertisements and promotional material; Cymbalta brand plans; Cymbalta market research; selected sales representative training materials; policies governing communication with health

[6] Plaintiffs allege that Lilly deliberately withheld unredacted versions of emails from Dr. Michael Detke, a former Cymbalta medical director, until after Dr. Detke was deposed because these emails were damaging to Lilly. *See* Pl.'s Mot. to Compel at 5 n.2. This allegation is entirely without foundation. Plaintiffs identified to Lilly 112 documents they believed were improperly redacted on April 6. Lilly re-reviewed those identified documents and produced revised versions where appropriate as rapidly as possible. Plaintiff's Exhibit 12 was produced in unredacted form on April 27, the day before Dr. Detke's deposition (contrary to Plaintiffs' assertion that it was produced during the deposition itself). *See* Reynolds Decl. Ex. 8. Additional documents were also produced on April 28, the day of Dr. Detke's deposition. Plaintiffs' counsel did not finish deposing Dr. Detke until 8 PM that evening, at which point he announced that he reserved the right to re-call Dr. Detke at a later time. *See* Detke Dep. at 269:24-25, 270:13-14. Lilly's counsel objected appropriately on the grounds that Dr. Detke had, by that point, been deposed for nearly seven hours and until late in the evening. *Id.* at 270:19-23. Furthermore, the unredacted sentence in Plaintiffs' Exhibit 12 *undermines* their theory that Prozac marketing caused Lilly to believe that discontinuation-emergent adverse events were significant: Dr. Detke states that according to a U.S. Prozac sales representative, the rate of discontinuation-emergent adverse events was "30th most important on a list of 30 issues by prescribers, and after concerted education on the issue, it moved all the way up to about 28th." CYM-R-01873415 [Pl.'s Ex. 12].

[7] To be clear, Lilly maintains that Plaintiffs' theory is not true and is unsupported by any evidence.

care providers by Lilly employees; packaging for Cymbalta samples left with physicians; and relevant emails from, to, and copying John Hixon, the Cymbalta brand team leader from pre-launch through 2006. *See* Def.'s Responses to Pl.'s First Set of Requests for Production of Documents at 27-33, Reynolds Decl., Ex. 9; Declaration of Jennifer A. Holmes ¶ 8 (Apr. 1, 2015), *Ali* dkt. 45-2; Declaration of Jeffrey Bozman (Apr. 1, 2015), Ex. W, *Ali* dkt. no. 45-3. If Plaintiffs cannot support their theory with these extensive completed productions, discovery on Prozac marketing will in no way contribute to their case.

In short, Lilly has acknowledged, studied, and warned of potential Cymbalta discontinuation symptoms since the product's development. Lilly's marketing materials for a separate, non-Cymbalta medicine will do nothing to illuminate this core point further.

II. The Burden of Plaintiffs' Proposed Discovery Outweighs Its Benefit

Even if Plaintiffs could demonstrate some minimal relevance of their requested discovery, the burden of collecting these Prozac materials far outweighs its likely benefit. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii), 26(c). Plaintiffs claim that their request is not burdensome because it is "laser-focused" on a production of a small number of documents. But the fact that Plaintiffs hope that the *result* of Lilly's search in response to their request will be a few key documents ignores the burden of the search itself: looking for needles in 30 years of hay is no simple task. Prozac was approved in the United States in 1987 and launched in 1988; Lilly still sells it today. Plaintiffs' request therefore requires Lilly to review nearly 30 years of documents with, according to Plaintiffs' counsel, a focus on the oldest years -- the least likely to be accessible and the most burdensome to resurrect.

Market Research Materials: As Plaintiffs are aware from previous litigation, Lilly's Singlepoint database is a repository of market research studies that was created in 2008. Material from the preceding market research database was imported into Singlepoint, with the

result that Singlepoint holds material from 2002 to the present. There is no systematic repository of market research from prior to 2002, and therefore collecting additional studies will be difficult. Pearson Decl. at 3.

Brand Plans: Lilly has no brand plan repository. As a result, locating brand plans requires a detailed, time-consuming search of individual files and custodians. For instance, in order to produce Cymbalta brand plans -- brand plans for a product launched just eleven years ago -- Lilly conducted email collections of six custodians who were members of the U.S. and global brand teams over a twelve-year period. Those collections, which required emails and other electronic documents to be restored from archives, included over 10,000 documents, which Lilly's counsel then had to further search in order to locate the brand plans ultimately produced. Reynolds Decl. ¶ 11. Because Prozac has been marketed for three times as long as Cymbalta, Lilly would be required to search comparatively more custodians over a longer period of time to find Prozac brand plans. Moreover, Lilly only began to fully archive emails sent by or to its employees in 2005, and thus many of the documents Plaintiffs seek are likely stored in archival hard copy among personal files and would require a hand review of voluminous hard copy documents that cannot be electronically searched by the use of search terms. *See id.* at ¶ 12. The burden of such a search, which Plaintiffs waited until the close of discovery to demand, is colossally disproportionate to any conceivable benefit that Plaintiffs would be able to derive from such documents in light of their marginal relevance.

Sales Materials: Relatedly, Plaintiffs seek sales aids used by Lilly in promoting Prozac which specifically mention Prozac's risk of discontinuation-emergent adverse events. As with brand plans, there is no single, centralized repository or database of Lilly's sales aids. *See id.* at ¶ 13. FDA submissions, including sales aids, have been collected in litigations related to Prozac,

but identifying the specific, responsive material requested by Plaintiffs will nonetheless require additional attorney review in this case prior to any production to Plaintiffs.

Plaintiffs have further increased the burden on Lilly by their delay in making these requests and contesting Lilly's responses. As demonstrated by the course of events described above, Plaintiffs were aware from before they filed their complaints that they intended to make allegations related to Prozac. Yet, despite this Court's direction to serve discovery immediately and its implementation of a scheduling order emphasizing rapid discovery, Plaintiffs did not include these Prozac-related requests in their initial set of 105 requests for production. When these requests were finally served -- only 30 days before the close of discovery as then set -- Lilly attempted to facilitate the timely resolution of this dispute by providing the specifications of its planned production with its objections, 15 days early. Nonetheless, Plaintiffs waited three more weeks to file this motion to compel such that it will now be heard on the last day of *extended* discovery. Any production by Lilly will thus have to be done on an accelerated schedule that will be extremely difficult to achieve given the age and unknown, scattered locations of the documents as described above.

None of these efforts will benefit the parties sufficiently to justify their expense. Plaintiffs have received -- and cite in their motion -- documents that indicate that discontinuation-emergent adverse events were considered in market research that Lilly performed on Cymbalta. They have likewise received (and cite) documents that refer to discontinuation-emergent adverse events in the context of Prozac market research from 2002 and onward, before Cymbalta was launched. If Plaintiffs' objective is indeed to prove that Lilly was aware of the risk of discontinuation-emergent adverse events before launching Cymbalta -- a fact that is not even in material dispute -- that awareness is fully established by the documents

already in their possession. Similarly, to the extent that Plaintiffs wish to establish that Cymbalta's marketing and promotion was impacted by Prozac's marketing, the documents relevant to that proposition are in already-produced Cymbalta-related discovery, not the Prozac marketing documents themselves. Finally, all of these issues are tangential at best to the core issues of the litigation: whether Lilly's warning accurately and adequately represented the risk of discontinuation-emergent adverse events from Cymbalta. The benefit that Plaintiffs will receive from these additional materials cannot, therefore, outweigh the expense that Lilly will be forced to bear in order to locate and produce marketing materials from a drug not at issue in this matter.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion to compel in its entirety.

Dated May 27, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of May, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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